SEP 11 2003

Exhibit V **510(k) Summary**

K 031801

(1) MANUFACTURER SUBMITTING 510(K) NOTIFICATION

Applicant	
	Blue X Imaging Srl Via Idiomi 3/16 20090 Assago Milan Italy Registration Number: _____ Contact Person Mr. Giuseppe Giacomini, CEO and General Manager phone: + 39 02 4571 2171, fax + 39 02 4570 3385 e-mail: giuseppe.giacomini@bluex.it

Designated Agent, Initial distributor in the USA	
	Chicago X-Ray Systems, Inc. 251 E. Dundee Road Suite #6 Wheeling, IL 60090 Registration Number: 1421874 Contact Person: Mr. Al Sosa, President phone: 847 459 3889, fax: 847 459 9214 e-mail: chicagox-ray@att.net

Manufacturing site	
	Blue X Imaging Srl Via Idiomi 3/16 20090 Assago Milan Italy

Prepared	
	May 1, 2003

(2) DEVICE NAME

The proprietary name of the device is "PantOs".

Trade name:

- "PantOs 16" for the versions which make use of traditional films with chemical processing or storage phosphor plates for digital read out, and
- "PantOs DG", for the versions which make use of a digital sensor.

The classification names of this devices are:

- "UNIT, X-RAY, EXTRAORAL WITH TIMER"
- "SYSTEM,X-RAY,EXTRAORAL SOURCE,DIGITAL"
- "SOLID STATE X-RAY IMAGER (FLAT PANEL/DIGITAL IMAGER".

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(3) LEGALY MARKETED DEVICE TO WHICH EQUIVALENCE IS CLAIMED

In this Pre-market notification; Rotograph Plus, manufactured by Villa Sistemi Medicali, is taken as device substantially Equivalent (SE) to PantOs 16.

The version of Rotograph Plus equipped with digital sensor DXIS by Signet or CDR Pan by Shick is substantially equivalent to PantOs DG.

- Rotograph Plus, with 510(k) number K972968, is manufactured by
  Villa Sistemi Medicali SpA.
  Via delle Azalee, 3 - 20090 Buccinasco Milan Italy
  Phone +39 02 488 591, Fax +39 02 488 1844.
- DXIS, digital panoramic sensor, with 510(k) number K983283,
  is manufactured by
  SIGNET S.A.S.
  115 bis blv du Général Giraud - 94100 Saint Maur des Fossés, FRANCE
  Phone +33 1 4883 7300, Fax +33 1 4883 7310,
- CDR Pan, digital panoramic sensor, with 510(k) number K982661,
  is manufactured by
  Schick Technologies, Inc.
  30-00 47th Avenue - Long Island City, NY 11101
  Phone 718-482-2159, Fax: 718-937-5962

(4) DEVICE DESCRIPTION

PantOs 16 is an X-ray equipment for dental panoramic radiography and for Cephalometry when completed with lateral arm (Ceph version.

PantOs 16 has an X-ray generator with anodic voltage from 60 to 86 kV (constant potential), anodic current from 4 to 10 mA (direct current).

Positioning the patient is done using a bite block or a chin rest, a few simple steps are required: once the height of the carriage is adjusted manually to bring the Frankfurt plane horizontally, correct rotation of the head is checked with the mirror. Front teeth alignment (to align to the in-focus-layer) is done by moving manually the carriage (backward or forward) till correct position is determined with the aid of the lateral light beam (the unit is adjusted without the need to move the patient).

PantOs DG performs like PantOs 16 and is equipped with a digital panoramic receptor instead of film cassette, thus producing panoramic images on the display of a computer system.

(5) INTENDED USE

The PantOs equipment, model PantOs 16 and PantOs DG are indicated for individuals requiring extra-oral dental radiographic examinations and diagnosis of diseases of the teeth, jaw, and oral structures. By using the system the user can expose and acquire radiographic images of the dentomaxillofacial region.

Depending on the model, the anatomical structures are visualized either on a radiographic film or on a computer display, through a dedicated image-intensified fluoroscopic x-ray system.

The intended use of PantOs 16 and PantOs DG is not altered but remains the same of the Rotograph Plus.

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(6) MAIN DIFFERENCES

As detailed in the specific section, the main differences of the PantOs 16 with respect to the SE device are here summarized:

- Cassette type: PantOs uses a flat cassette of 15x30 cm (about 5.9x11.8 inches), while Rotograph plus uses a curved one of 5x12 inches (smaller picture).
- X-ray generator: PantOs uses a high frequency generator which allows for direct current supply (constant potential, instead of pulsed, also featuring fine control of radiographic technique factors (kV, mA, and mAs), and stability, independently from possible fluctuations of the mains voltage.
- Focal Trough: PantOs gives the user the possibility to adjust the position of the rotating carriage to better fit patient anatomical structures into the focal trough, thus allowing for optimized panoramic projection on different clinical cases.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Blue X Imaging Srl
% Mr. Al Sosa
Chicago X-Ray Systems, Inc.
251 E. Dundee Road Suite #6
WHEELING IL 60090

AUG 23 2013

Re: K031801
Trade/Device Name: PantOs 16 and GD
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH, EHD, and MQB
Dated: May 14, 2003
Received: June 13, 2003

Dear Mr. Sosa:

This letter corrects our substantially equivalent letter of September 11, 2003.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Exhibit III Indication for Use Statement

510(k) Number (if known): K031801

Device Name: **PantOs**

Indication For Use :

The PantOs equipment, model PantOs 16, and PantOs DG are indicated for individuals requiring extra-oral dental radiographic examinations and diagnosis of diseases of the teeth, jaw, and oral structures. It exposes and acquires radiographic images at the dentomaxillofacial region. Depending on the model, the anatomical structures are visualized either on a radiographic film or on a computer display, through a dedicated image-intensified fluoroscopic x-ray system.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Prescription Use ✓

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K031801